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Part VI

Environmental Protection Agency

40 CFR Part 799

Toxic Substances; Testing Regulations: Neurotoxicity and Acetone, etc.; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPPTS–42134F; FRL–4924–7]

RIN 2070–2033

Revocation of Final Multi-substance Rule for the Testing of Neurotoxicity

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule Revocation.

SUMMARY: This document announces EPA's decision to revoke the Multi-Substance Rule for the Testing of Neurotoxicity, that required manufacturers and processors of acetone (CAS No. 67–64–1), technical grade *n*-amyl acetate (CAS No. 628–63–7), 1-butanol (CAS No. 71–36–3), *n*-butyl acetate (CAS No. 123–86–4), diethyl ether (CAS No. 60–29–7), 2-ethoxyethanol (CAS No. 110–80–5), ethyl acetate (CAS No. 141–78–6), isobutyl alcohol (CAS No. 78–83–1), methyl isobutyl ketone (CAS No. 108–10–1), and tetrahydrofuran (CAS No. 109–99–9) to conduct testing for neurotoxicity. EPA is revoking this rule as part of a settlement agreement reached with the manufacturers of these chemicals, who have agreed to perform certain neurotoxicity and *in vivo* hydrolysis testing of 7 of the 10 chemicals under enforceable consent agreements (''ECAs'').

EFFECTIVE DATE: January 23, 1995.

ADDRESSES: A public version of the administrative record supporting this action, with any confidential business information deleted, is available for inspection at the TSCA Nonconfidential Information Center, also known as the TSCA Public Docket Office (7407), Rm. NE B607, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460 from 12 noon to 4:00 p.m. Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Susan Hazen, Director, Environmental Assistance Division, (7408), Office of Pollution Prevention and Toxics, 401 M St., SW., Washington, DC 20460, (202) 554–1404, TDD (202) 554–0551.

SUPPLEMENTARY INFORMATION: EPA has determined that it is appropriate to revoke the multi-substance rule for the testing of neurotoxicity because the manufacturers of 7 of the 10 chemicals subject to the final test rule have agreed to conduct a modified set of neurotoxicity and *in vivo* hydrolysis testing under ECAs that accomplish many of the goals of the test rule. The following seven chemical substances will be tested pursuant to ECAs: acetone (CAS No. 67–64–1), technical grade *n*-amyl acetate (CAS No. 628–63–7), *n*-butyl acetate (CAS No. 123–86–4), ethyl acetate (CAS No. 141–78–6), isobutyl alcohol (CAS No. 78–83–1), methyl isobutyl ketone (CAS No. 108–10–1), and tetrahydrofuran (CAS No. 109–99–9). Testing is currently underway for *n*-butyl acetate and isobutyl alcohol. *In vivo* hydrolysis testing will be conducted on butyl acetate to determine if its test results for neurotoxicity can be used to assess the neurotoxicity of its metabolite, 1-butanol.

I. Background

On July 27, 1993 (58 FR 40262) EPA issued a test rule under TSCA section 4 that required manufacturers and processors of 10 substances to conduct testing for neurotoxicity (Ref. 1). The test rule required all the testing proposed for the 10 substances on March 4, 1991 (56 FR 9105). The required testing was the same for all 10 substances and included acute and subchronic functional observational battery and motor activity, and subchronic neuropathology and schedule-controlled operant behavior (SCOB). These 10 substances are listed below:

Chemical name	CAS No.
acetone	67–64–1
n-amyl acetate, technical grade	628–63–7
1-butanol	71–36–3
n-butyl acetate	123–86–4
diethyl ether	60–29–7
2-ethoxyethanol	110–80–5
ethyl acetate	141–78–6
isobutyl alcohol	78–83–1
methyl isobutyl ketone	108–10–1
tetrahydrofuran	109–99–9

The manufacturers of these substances petitioned for review of the final rule under TSCA section 19 in the Fifth Circuit Court of Appeals (Ref. 2). Subsequent to the filing of this challenge to the rule, EPA, the Chemical Manufacturers Association (''CMA''), and authorized representatives of all parties challenging the rule, entered into settlement negotiations to resolve the lawsuit.

As a result of these settlement discussions, the parties to the lawsuit agreed, subject to certain conditions set forth in the settlement agreement (Ref. 3), to conduct neurotoxicity and *in vivo* hydrolysis testing of 7 chemical substances under ECAs to be negotiated pursuant to EPA regulations. Testing on two of the chemicals subject to the final rule, *n*-butyl acetate and isobutyl alcohol, was already underway. It was CMA's and the test sponsors stated intent that such testing continue on schedule during the pendency of this proceeding (Ref. 3).

In turn, EPA agreed to propose to withdraw the final test rule. EPA was aware that the settlement agreement contemplated testing fewer chemicals and a reduced set of testing on some of those chemicals than the testing regimen required by the final rule. Although EPA believed that the rulemaking record contained substantial evidence to support the testing requirements in the final rule, EPA believed that the settlement agreement was in the public interest as it allowed testing to proceed on an expedited basis, without the uncertainties of protracted litigation. CMA's lawsuit was dismissed without prejudice by the 5th Circuit Court of Appeals on May 13, 1994, in response to a joint motion for a stay, but it can be reinstated by either party upon filing of a letter with the court (Ref. 4).

On June 27, 1994, EPA published three notices in the **Federal Register**: a Stay of the final test rule (59 FR 33184), a proposal to revoke the final test rule (59 FR 33187), and an announcement of a public meeting to initiate negotiation of consent agreement testing (59 FR 33191). The Stay suspended all requirements of the final test rule until EPA either lifted the Stay or revoked the test rule. Final revocation of the test rule was conditional on the successful negotiation of testing to be performed under ECAs. The public meeting announcement solicited interested parties to participate in the negotiation and/or observation of negotiations. On July 28, 1994, EPA held the public meeting to initiate the negotiations. The ECAs which resulted were signed in November 1994 and January 1995 and required the neurotoxicity and *in vivo* hydrolysis testing of the following 7 substances:

Substance	Tests
acetone	SCOB (subchronic)
n-amyl acetate, technical grade	Functional Observational Battery (acute and subchronic), Motor Activity (acute and subchronic), Neuropathology (subchronic)
n-butyl acetate	Functional Observational Battery (acute and subchronic), Motor Activity (acute and subchronic), Neuropathology (subchronic), SCOB (subchronic), *In Vivo* Hydrolysis
ethyl acetate	Functional Observational Battery (acute and subchronic), Motor Activity (acute and subchronic), Neuropathology (subchronic), SCOB (subchronic)
isobutyl alcohol	Functional Observational Battery (acute and subchronic), Motor Activity (acute and subchronic), Neuropathology (subchronic), SCOB (subchronic)
methyl isobutyl ketone	SCOB (subchronic)
tetrahydrofuran	Functional Observational Battery (acute and subchronic), Motor Activity (acute and subchronic), Neuropathology (subchronic)

The ECA testing program and negotiations are described more fully in the announcement of the signing of the ECAs, published elsewhere in this **Federal Register**. Compared with the final rule, the above testing program represents a retention of the full set of tests for three chemicals (*n*-butyl acetate, ethyl acetate, and isobutyl acetate), a reduction in tests for four chemicals (acetone, *n*-amyl acetate, methyl isobutyl ketone, and tetrahydrofuran), and an elimination of testing for three chemicals (1-butanol, diethyl ether, and 2-ethoxyethanol). It is anticipated, however, that the *in vivo* hydrolysis test of *n*-butyl acetate may indicate that the separate testing of 1-butanol may not be necessary, and because of this, 1-butanol manufacturers have agreed to share in the cost of *n*-butyl acetate testing. The evaluation of the metabolic fate of butyl acetate will be performed in a study of its *in vivo* hydrolysis to 1-butanol. If the conversion of butyl acetate to 1-butanol is sufficiently rapid and complete, EPA may determine that the neurotoxic effects of 1-butanol can be predicted from the results of butyl acetate testing. If this is not the case, EPA may consider reproposing separate testing of 1-butanol.

As mentioned above, a third notice was published on June 27, 1994 (59 FR 33187), which proposed to revoke the final multi-substance rule for the testing of neurotoxicity. This notice allowed all interested parties an opportunity to evaluate and comment on EPA's proposed revocation of the final rule and decision to pursue ECAs as the mechanism for achieving testing.

II. Public Comments

EPA received one comment on the proposed revocation. This comment was from CMA and supported EPA's proposal to revoke the test rule and enter consent agreement negotiations (Ref. 5).

The public meeting to initiate negotiation of consent agreement testing was held on July 28, 1994. No new interested parties identified themselves to EPA at this meeting or during the 30–day comment period. During the meeting, the only comment concerning the proposed revocation came from CMA's legal counsel, and related to procedures for simultaneous signing of the ECAs and the revocation.

III. Revocation of Final Test Rule

EPA is revoking the final Multi-Substance Rule for the Testing of Neurotoxicity (40 CFR 799.5050) based upon the reasons stated in the proposed revocation (59 FR 33187, June 27, 1994, Unit II), the lack of comments opposing the revocation, and the successful negotiation of ECAs. EPA believes the decision to allow manufacturers of these substances to conduct neurotoxicity and *in vivo* hydrolysis testing under ECAs will allow for the most timely development and public availability of data to assess the potential neurotoxicity of these compounds. While EPA acknowledges that the testing that will be conducted under ECAs will not be as extensive as that required by the final test rule, EPA believes that use of the ECA process will result in the fastest development of data. Testing and data development will proceed without the potentially lengthy delay of testing pending resolution of costly litigation on the merits of the final test rule.

IV. Rulemaking Record

EPA has established a record for this revocation under docket number OPPTS–42134F. This record contains the following information:

A. Supporting Documentation

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Notice of proposed multi-substance rule for the testing of neurotoxcity (56 FR 9105, March 4, 1991).

(b) Notice of final multi-substance rule for the testing of neurotoxicity (58 FR 40262, July 27, 1993).

(c) Notice announcing administrative stay of final multi-substance rule for the testing of neurotoxicity (59 FR 33184, June 27, 1994).

(d) Notice of proposed revocation of final multi-substance rule for the testing of neurotoxicity (59 FR 33187, June 27, 1994).

(e) Notice announcing opportunity to participate in negotiations for neurotoxicity testing; solicitation for interested parties (59 FR 33191, June 27, 1994).

(2) Communications consisting of:

(a) Written letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries (including public meeting on July 28, 1994).

B. References

(1) Final multi-substance rule for the testing of neurotoxicity (58 FR 40262, July 27, 1993).

(2) Chemical Manufacturers Association (CMA). Petition for Review. Filed with United States Court of Appeals for the Fifth Circuit. (October 8, 1993).

(3) United States Court of Appeals for the Fifth Circuit. Settlement Agreement between Environmental Protection Agency (USEPA) and petitioners. No. 93–5381. (April 28, 1994).

(4) United States Court of Appeals for the Fifth Circuit. Dismissal of petitioners appeal against EPA. No.93–5381. (May 13, 1994).

(5) Latham & Watkins (legal counsel to CMA), Washington, DC. Comment on proposed revocation of final multi-substance rule for the testing of neurotoxicity. Submitted to TSCA Docket Office, USEPA, Washington, DC.(July 20, 1994).

The public record for this rulemaking is available for inspection in the TSCA Nonconfidential Information Center (also known as the TSCA Public Docket Office), Rm. NE B607, 401 M St., SW., Washington, DC from 12 noon to 4:00 p.m., Monday through Friday, except legal holidays.

V. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis and review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (aka ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. Pursuant to the terms of this order, EPA has determined that this rule would not be ''significant''.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., EPA is certifying that revocation of this test rule will not have a significant impact on a substantial number of small businesses because only the 24 manufacturers who signed the ECAs, which will replace the revoked test rule, will be responsible for conducting and paying for the testing. None of these manufacturers are small businesses.

C. Paperwork Reduction Act

There are no information collection requirements associated with this revocation covered under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

List of Subjects in 40 CFR Part 799

Chemicals, Chemical export, Environmental protection, Hazardous substances, Health effects, Laboratories, Reporting and recordkeeping requirements, Testing.

Dated: January 10, 1995.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR, chapter I, subchapter R, part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

§799.5050—[Removed]

2. By removing §799.5050.

[FR Doc. 95–1673 Filed 1–20–95; 8:45 am]

BILLING CODE 6560–50–F

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40 CFR Part 799

[OPPTS–42134G; FRL–4924–8]

RIN 2070–2033

Testing Consent Orders for Acetone, n-Amyl Acetate, n-Butyl Acetate, Ethyl Acetate, Isobutyl Alcohol, Methyl Isobutyl Ketone, and Tetrahydrofuran

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Testing Consent Agreements and Orders.

SUMMARY: EPA has issued Testing Consent Orders (Orders) that incorporate Enforceable Consent Agreements (ECAs) pursuant to the Toxic Substances Control Act (TSCA) with companies who have agreed to perform certain neurotoxicity tests with the following seven substances: acetone (CAS No. 67–64–1), *n*-amyl acetate (CAS No. 628–63–7), *n*-butyl acetate (CAS No. 123–86–4), ethyl acetate (CAS No. 141–78–6), isobutyl alcohol (CAS No. 78–83–1), methyl isobutyl ketone (CAS No. 108–10–1), and tetrahydrofuran (CAS No. 109–99–9). This document summarizes the requirements of the ECAs and amends 40 CFR 799.5000 by adding these seven substances to the list of chemical substances and mixtures subject to ECAs. Accordingly, the export notification requirements of 40 CFR part 707 apply to these substances.

EFFECTIVE DATE: January 23, 1995.

ADDRESSES: A public version of the administrative record supporting this action, with any confidential business information deleted, is available for inspection at the TSCA Nonconfidential Information Center, also referred to as the TSCA Public Docket Office (7407), Rm. NE B607, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460 from 12 noon to 4:00 p.m. Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Susan Hazen, Environmental Assistance Division, Office of Pollution Prevention and Toxics, 401 M St., SW., (7408), Washington, DC 20460, (202) 554–1404, TDD (202) 554–0551.

SUPPLEMENTARY INFORMATION: Twelve companies that include AlliedSignal, Inc., Aristech Chemical Corp., BTL Specialty Resins Corp., The Dow Chemical Co., Eastman Chemical Co., Exxon Chemical Co., General Electric Co., Georgia Gulf Corp., Goodyear Tire & Rubber Co., Shell Oil Co., Texaco Refining & Marketing, Inc., and Union Carbide Corp. have agreed to perform neurotoxicity testing with acetone. The Union Carbide Corp. has agreed to perform neurotoxicity testing with *n*-amyl acetate. Nine companies that include Aristech Chemical Corp., BASF Corp., BP Chemicals Inc., Eastman Chemical Co., Hoechst Celanese Chemical Group, Inc., Rhone-Poulenc Inc., Shell Oil Co., Union Carbide Corp., and Vista Chemical Co. have agreed to perform neurotoxicity testing with butyl acetate. Six companies that include BP Chemicals Inc., Eastman Chemical Co., Hoechst Celanese Chemical Group, Inc., Monsanto Co., Rhone-Poulenc Inc., and Tolson USA, Inc. have agreed to perform neurotoxicity testing with ethyl acetate. Five companies that include BASF Corp., Eastman Chemical Co., Hoechst Celanese Chemical Group, Inc., Shell Oil Co., and Union Carbide Corp. have agreed to perform neurotoxicity testing with isobutyl alcohol. Six companies that include Eastman Chemical Co., Exxon Chemical Co., Hoechst Celanese Chemical Group, Inc., Rhone-Poulenc Inc., Shell Oil Co., and Union Carbide Corp. have agreed to perform neurotoxicity testing with methyl isobutyl ketone. Six companies that include Arco Chemical Co., BASF Corp., E.I. duPont de Nemours and Co., GE Plastics, ISP Management Company, Inc., and QO Chemical Inc. have agreed to perform neurotoxicity testing with tetrahydrofuran.

I. Background

On March 4, 1991 (56 FR 9105), EPA proposed neurotoxicity testing of 10 substances under section 4 of TSCA. All 10 substances have wide use as solvents (Refs. 10 and 11). A TSCA section 4(a)(1)(B) finding for substantial exposure was made for each substance based on production volume, occupational and consumer exposure,